

### **REMARKS**

Reconsideration of the application is respectfully requested.

Claims 1 and 14 have been amended to recite that the proteolytic enzyme is papain, bromelain, or a mixture thereof, and to recite that the composition “is substantially free of D-carnitine.” Support for these amendments is found in the specification at, e.g., ¶¶ [5], [6], and [25]. Claim 5 has been canceled without prejudice or disclaimer. No new matter has been added to the application. Claims 1, 4, and 6-23 are pending in this application. Since claims 11-13 have been withdrawn from consideration, only claims 1, 4, 6-10, and 14-23 are currently at issue.

### **Indefiniteness Rejection**

Claims 1-10, 18, and 20-23 have been rejected as indefinite. Specifically, claim 1 has been rejected due to the phrase “or a mixture thereof” at lines 6 and 7 of the claim. According to the Examiner, the intended mixtures are not sufficiently delineated and it is unclear, for example, whether the first mixture is a mixture of enzymes or a mixture of enzymes and hydroxy acids.

In order to expedite prosecution, and without disclaimer, claim 1 has been amended to clarify that the phrase “a mixture thereof” refers to a mixture of the recited enzymes. Accordingly, applicants respectfully submit that amended claim 1 is definite.

The Examiner argues that there is a lack of antecedent basis for the term “a papain” in claims 18, 22, and 23. These claims depend from claims 1 and 14, both of which recite papain as a proteolytic enzyme. Accordingly, Applicants respectfully submit that there is antecedent basis for this term.

Claims 22 and 23 have been rejected for reciting “proteolytic units (PU)” for “a papain.” According to the Examiner, it is unclear what is signified by the term “PU units.”

Applicants respectfully submit that the term “PU units” is known in the art to refer to the quantity of the enzyme required to liberate the equivalence of one microgram of tyrosine per hour. *See* the specification at, e.g., ¶ [25].

For the foregoing reasons, withdrawal of this rejection is respectfully requested.

### **Anticipation Rejection**

Claims 1, 4, 10, and 14-17 have been rejected as anticipated by U.S. Patent Publication No. 2003/0175232 (“Elliott”) in view of Enzyme Nomenclature (<http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/4/21/62.html>). According to the Examiner, Elliott discloses a topical composition comprising L-carnitine, the enzyme subtilisin, and one or more hydroxy acids.

Claims 1 and 14 have been amended to delete pepsin, peptidase, trypsin, enterokinase, and alpha chymotrypsin from the list of proteolytic enzymes recited in the claims. The proteolytic enzymes recited in the amended claims are papain and bromelain. Subtilisin is not encompassed by the list of proteolytic enzymes in the claims.

Further, Elliot discloses use of racemic carnitine (*see* Elliot at, e.g., ¶ [0041]), but is silent with respect to use of the L-enantiomer (i.e., L-carnitine).

Accordingly, Elliott does not anticipate the presently claimed topical composition, and Applicants respectfully request withdrawal of this rejection.

### **Obviousness Rejection**

Claims 1, 4-10, and 14-19 have been rejected as obvious over Elliott in view of U.S. Patent No. 6,149,924 (“Paul”), European Patent No. EP 0 631 779 (“Cavazza”), and U.S. Patent Nos. 3,683,939 (“Johnsen”), 6,416,759 (“Vromen”), 5,589,505 (“Yu”), and 5,968,528 (“Deckner”). Paul is cited by the Examiner for disclosing L-carnitine and a hydroxy acid. Cavazza is cited for teaching the use of various additives in compositions. Johnsen is cited for teaching that the pH of cosmetics is favorable in the range of 5.5 to 7. The Examiner states that Vromen demonstrates that proteolytic enzymes such as papain are routinely added to cosmetic and topical compositions. The Examiner further contends that Yu and Deckner disclose addition of skin bleaching agents to cosmetic compositions. Deckner is also cited for disclosing the use of carnitine and hydroxy acids in topical compositions and a pH range of 5-8. According to the Examiner, it would have been obvious to modify the compositions disclosed by Elliott and Paul by addition of the various additives taught by Cavazza, Johnsen, Vromen, Yu, and Deckner.

The rejection is traversed and reconsideration is respectfully requested.

Applicants respectfully submit that the Examiner is using hindsight to reconstruct the present invention. As mentioned above, Elliott does not specifically disclose L-carnitine. Racemic carnitine is only disclosed in Elliott as one possible osmo-protectant in a list of several other compounds.

The Cavazza reference is directed to the use of esters of L-carnitine and acyl-L-carnitine, but is silent with regard to compositions comprising unmodified L-carnitine and salts thereof (as required by the pending claims). A skilled artisan, therefore, would not apply the teachings of Cavazza to an L-carnitine formulation (which does not contain an ester of L-carnitine or acyl L-

carnitine). Furthermore, if Cavazza were combined, a skilled person would use an ester of L-carnitine or acyl L-carnitine as taught by Cavazza in lieu of L-carnitine itself.

Johnsen discloses the use of proteolytic enzymes in one step of the production process for skin care compositions, however, the enzymes are subsequently deactivated. *See* Johnsen at col. 4, lines 64-68 (“To terminate the enzyme action, the solution is heated ...”) and col. 9, lines 38-53. The proteolytic enzymes are used to hydrolyze a proteinaceous material, but are not intended to be included in the final product in active form (see, for example, col. 2, lines 4-17, of Johnsen). Thus, one of ordinary skill in the art would not have been motivated to apply the teachings of Johnsen to the claimed composition containing active enzyme.

Further, the hydroxy acid and claimed additive agents are recited in the cited references as optional agents and are listed among dozens of other reagents. *See, e.g.,* Paul at col. 14, lines 35-57, and col. 15, line 16; Yu at col. 2, lines 15-38; and Deckner at col. 31, lines 41-59. The Examiner provides no reason as to why the skilled artisan would have specifically selected the reagents recited in the pending claims from the vast number of compounds disclosed in the cited prior art.

Finally, none of the cited references disclose the unexpected results of improved exfoliation performance achieved with the claimed composition. *See* the February 12, 2009 Response; *see also* specification at, e.g., pages 4, and 25-27, and Figures 1 and 3. Paul, Elliot, Cavazza, Johnsen, Vromen, Yu, and Deckner all fail to teach or suggest that a correlation exists between pH and exfoliation performance. Accordingly, one of ordinary skill in the art would not have expected that adjusting the pH of the specific components recited in the claims would produce significantly improved exfoliation.

For at least the above reasons, claims 1, 4, 6-10, and 14-23 are not obvious over the cited references. Applicants respectfully request that the rejection be withdrawn.

**CONCLUSION**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered, and that the pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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